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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,266	ONG ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,26 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,26 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1, 2, 3, 26, 29 and 30 have been amended and claims 33-34 newly added, as requested in the amendment filed on September 8, 2009. Following the amendment, claims 1-3, 6, 26 and 29-34 are pending in the instant application and are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on September 8, 2009 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The amendments to the claims have successfully overcome the rejection of Claims 1-3, 6, 26 and 29-31 under 35 U.S.C. 112, second paragraph.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. The Declaration of Dr. Sylvie Marleau under 37 CFR 1.132 filed September 8, 2009 is sufficient to overcome the rejection of claims 26 and 31-32 under 35 U.S.C. 112, first paragraph, written description.

7. Claims 1-3, 6, 26, and 29-34 stand as rejected under 35 U.S.C. 112, first paragraph, scope of enablement, for reasons of record in the Office action mailed September 8, 2009. The rejection is based upon the method of the invention encompassing administering *any* one or more GHRP (Claim 1) or *any* CD36 ligand. Dependent claims recite that the method requires a GHRP "that does not induce secretion of growth hormone", but the independent claims are broadly drawn to compounds without this limitation.

As stated in the Marleau Declaration filed September 8, 2009, the prior art identifies "dozens of preferred GHRP analogs that induce GH secretion and more than a dozen preferred GHRP analogs lack the ability to induce growth hormone secretion … In addition ..., other compounds that bind to the hexarelin binding site on CD36 were known … these include the polyconal [*sic*] rabbit anti-rat CD36 (A 371 antibody" (at ¶ 11-12).

In traverse of the rejection Applicant states in Remarks (pages 8-9):

> Firstly, the results of Example 1 demonstrate the ability of hexarelin to prevent development of atherosclerosis and to reduce total plasma cholesterol. Second, the results of Example 2 simply demonstrate the dosage of hexarelin administered for 4 weeks was insufficient in producing a statistically significant reduction in lesion size following atherosclerosis development for 8 weeks prior. A modest decrease was nevertheless measured. The result with EP80317 was also statistically insignificant for the 4 week treatment, but it was significant for the 6 week and 8 week treatments. Unfortunately, 6 and 8 week treatments

> using hexarelin are not described. Given the results demonstrated with hexarelin and EP80317 in Examples 1 and 2, persons of skill in the art would have expected hexarelin to be effective following longer duration and possibly at higher dosages for the treatment of atherosclerosis. (*Emphasis added*)

While the arguments and Declaration under CFR 1.132 have been considered in full, they are not found persuasive to overcome the rejection for the following reasons.

As stated above, the methods broadly encompass a vast array of GHRPs, including ones which do and do not induce secretion of growth hormone, and a further array of CD36 ligands. Firstly, from what is disclosed in the specification, it is not even clear whether the method requires that the GHRP does not induce secretion of growth hormone or not. Secondly, the working examples using two GHRPs that do not induce GH secretion, hexarelin and EP80317, demonstrate unpredictable results upon "administering to the patient for four or more weeks". Furthermore, there is nothing of record to suggest that the method can be performed with a reasonable expectation of success to treat or prevent atherosclerosis comprising administering to a patient for four or more weeks *any* GHRP or *any* CD36 ligand.

The standard of an enabling disclosure is not what a person of skill in the art "would have expected … to be effective following longer duration and possibly at higher dosages" than what is specified in the instant claims. The standard for enablement is one of the ability to make and use the method of the claims to treat or prevent atherosclerosis with a reasonable expectation of success by following the specific guidance and direction within the instant specification. The Examiner maintains the position that a patent is granted for a completed invention, not the general suggestion of

an idea and how that idea might be developed into therapeutic treatment or prophylaxis. In *Genentech, Inc, v. Novo Nordisk*, 42 USPQ 2d 1001, (CAFC 1997), the court held that:

> "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable". The court further stated that "when there is no disclosure … of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement".

The instant specification is not enabling and a skilled artisan would have to make a substantial inventive contribution in order to practice the method commensurate in scope with the claims.

Allowable Subject Matter

8. Claim 34 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action and written in independent form.

Conclusion

9. No Claim is allowed.

10. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and F 5:30 to 2, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane

Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649